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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/691,581	10/24/2003	Erich P. Lerchenfeld	07738.0173-01000	6955

7590 08/02/2005
Finnegan, Henderson, Farabow
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EXAMINER

PADEN, CAROLYN A

ART UNIT PAPER NUMBER

1761

DATE MAILED: 08/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/691,581

Applicant(s)

LERCHENFELD ET AL.

Examiner

Carolyn A. Paden

Art Unit

1761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>various</u> . | 6) <input type="checkbox"/> Other: _____ |

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-24 & 32-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zawistoski (2002/0048606 or WO 00/45648).

Zawistoski discloses a method of preparing microparticles of phytosterols and phytostanols. It is very well known in the art that phytostanol is the hydrogenated version of a phytosterols. From the pg Pub at page 3, paragraph 0040, the particle size of the starting material is described to preferably be at 100 microns. At page 2, paragraph 0017, the microparticles are described as having the particle size of the claims. At example 1, yoghurt is prepared with microparticulates of phytosterols and/or phytostanols by mixing phytosterols with milk powder and milk, allowing the milk mix to stand at room temperature and then homogenizing the combination in a

microfluidizer. In this case milk is regarded to be an aqueous material. The pressure used in the microfluidizer is disclosed at page 2, paragraph 0025. The use of emulsifiers in the product is shown at page 3, paragraph 0039. The claims appear to differ from Zawistoski in the recitation of the particle size of the starting material. But liquid milk is typically refrigerated so the mixture would have been heated by the exposure to room temperature conditions but no unobvious or unexpected result is seen from the difference, particularly with the final particle size falls within the range of the claims. It is also appreciated that the low treatment pressure of claims 76-80 is not mentioned but no unobvious or unexpected result is seen from the difference in the homogenization pressure. Although viscosity is not mentioned, this property is an inherent feature to the product produced by the process. No unobvious or unexpected result is seen from the suggestion of the product viscosity. Claim 102 calls for a particle size distribution in the form of a bell curve. No unobvious or unexpected result is seen from such a particle size distribution. One of ordinary skill in the art would expect that a ground particle would have a distribution in of particle sizes.

Claims 1-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoon (2002/0064548).

Yoon discloses dispersing plant sterol in an aqueous phase and then adding it to beverages, including juice. Sitostanol, the hydrogenated form of sitosterol, is a selected phytosterol at page 2, paragraph 25. At page 3, column 2, the process is described whereby plant sterol is mixed with an emulsifier and heated to 200°C. Then the mixture is treated to high speed stirring and homogenization. The distribution of the particle sizes is shown on Table 4. The claims appear to differ from Yoon in the recitation of the particle size of the starting material. No unobvious or unexpected result is seen from the selection of a particular particle size in Yoon particularly when the plant sterol is basically melted during the process. Although viscosity is not mentioned, this property is an inherent feature to the product produced by the process. No unobvious or unexpected result is seen from the suggestion of the product viscosity. Claim 102 calls for a particle size distribution in the form of a bell curve. No unobvious or unexpected result is seen from such a particle size distribution. It is appreciated that citrus beverage

is not mentioned but citrus or orange juices are the most popular juices consumed.

Claims 1-24 & 32-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rogers (6,391,370)

Rogers discloses treating phytosterols or phytostanol with an emulsifier and melting it. Then the combination is milled to a particle size of about 10 microns. The claims appear to differ from Yoon in the recitation of the particle size of the starting material. No unobvious or unexpected result is seen from the selection of a particular particle size in Yoon particularly when the plant sterol is basically melted during the process. Although viscosity is not mentioned, this property is an inherent feature to the product produced by the process. No unobvious or unexpected result is seen from the suggestion of the product viscosity. Claim 102 calls for a particle size distribution in the form of a bell curve. No unobvious or unexpected result is seen from such a particle size distribution.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-43 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-117 of copending Application No. 10/458,692. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the present application are open to the inclusion of the heating step required in the prior application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The references to Stohler (WO 99/39715), Tiainen (6,129,944 or WO 98/13023) and Yoon (2004/0029844 or 2005/0118203) are

cited to show particle size reduction of phytosterols in liquid solution for edible composition and a cumulative.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn A Paden whose telephone number is (571) 272-1403. The examiner can normally be reached on Monday to Friday from 7 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano, can be reached on (571) 272-1398 or by dialing 571-272-1700. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



CAROLYN PADEN 1761
PRIMARY EXAMINER 7-29-05